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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,475	08/20/2001	Olav K. Lyngberg	110.00810101	7111

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,475	LYNGBERG ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 48, 100-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 48 and 100-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 3/3/2004 has been received and entered into record and considered.

Claims 109-110 are added.

Currently, claims 1-24, 48, 100-110 are pending for examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-4, 11-16, 18, 22, 109-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 3, "latex-derived material formed by coalescence of latex-derived polymer particles" is vague and indefinite. It is unclear what specific "coalescence step" applicant is referring to. Similarly, claims 2-4, 11-16, 18, 22, 109-110 share the same problem as in claim 1.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6, 7, 9-13, 15, 18, 22, 48, 100-105, 107-110 are rejected under 35 U.S.C. 102(b) as being anticipated by Thiagarajan et al. (European Federation of Biotechnology, 1995, page 304-312)

Thiagarajan et al. teach immobilizing viable bacterial on biofilm for measuring oxygen consumption. (See Introduction) Thiagarajan et al. teach mixing E. Coli with non-toxic latex polymers and to form the bacteria/latex biostructure. (page 306, last paragraph) The biostructure is desiccation tolerant since the process involving dryness. (page 308, first paragraph) The device also containing a non-porous latex derived material for the coating plates. (See Figure 2) The device can detect oxygen consumption by E. Coli and inherently contains elements of transmitter and detector. (See Figures 6-8)

With respect to the feature of “coalescence of latex-derived polymer particles”, it is a natural attraction between particles to “coalescence” together during the preparing process. Furthermore, the instant invention directs to a product, i.e. a composite biological device. As long as the prior art contains the same material as recited in the claim(s), the reference inherently anticipates the claimed device. It is irrelevant how the material is made since no patentable weight is given to the process of making the materials in the device/or product claim.

3. Claims 1, 4-10, 14-15, 18-20, 100-110 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantwell et al. (EP 0288203)

Cantwell et al. teach a composite biological composition comprising immobilizing metabolically active cells on the nonporous polymers, e.g. latex. (See abstract) Cantwell et al. teach that admixtures cells with the nonporous latex to form agglomerates resulting in intertwining or imbedding cells with the polymers. (page 3- page 4) The cells are

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selected from bacteria and fungi. (page 4, third paragraph) Bacteria containing certain detectable enzyme, such as catalase, oxygenase, dehalogenase, could be inherently genetically manipulated into different strain. (page 6, example 1; claim 1-8) The cells and each polymer were used at a concentration of 10% w/v. (page 6-8) The immobilizing cells on the latex is by several forces, including cross-link. (page 2, line 25-30) The composition is inherently desiccation tolerant because the composition is in a colloidally stable condition when mixing with cells, and using polyvinylidene chloride polymer which intends to be a water barrier. (page 4, line 45-57) Similarly, the feature of "coalescence" of latex-derived polymer particles is not given patentable weight because it is a method of how to make the materials. As long as the reference contains the same material as recited in the claim language, the prior art reference inherently anticipates the claimed invention.

4. Claims 1-3, 6-22, 48, 100-110 are rejected under 35 U.S.C. 102(a) as being anticipated by Nova et al. (US 5751629)

Nova et al. teach a composition for molecular tracking and identification comprising matrices where the matrices are latex polymers and joining or linking to phage, eukaryotic cells, prokaryotic cells or bacteria which are metabolic active biological organisms. (Col. 6, line 15-36; claims 1-4) The linking process can be done with various means, including disulfide linkage or thioether bonds. (Col. 20, line, 54-65) The composition contains transmitter and detector for signal detection depending on various needs, including identifying nucleic acid, peptides or proteins. (Col. 5, line 12-30; Figure 6-7) The composition taught by Nova et al. also includes non-porous latex channel or microtiter plates. (see Figure 7 and Col. 6, line 20-35) Nova et al. also teach using mass spectrometry, thin layer chromatography, gel electrophoresis, or HPLC to purify samples. Thus, the composition of Nova et al. can be adapted to the aforementioned equipments and include electrodes and wires. (Col. 14, line 24-35) Nova et al. also teach using the composition to simultaneously determine large numbers of analytes in any format, e.g. phage library, because each known analyte data have been recorded and stored in the

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system. (Col. 34, line 2-15; claims 1-8) With respect to the feature of “coalescence” of latex-derived polymer particles, no patentable weight is given because it is a method of how to make the materials. As long as the reference contains the same material as recited in the claim language, the prior art reference inherently anticipates the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 23-24 rejections under 35 U.S.C. 103(a) as being unpatentable over Nova in view of Wagner et al. (US 6475808), are maintained.

Nova et al. reference has been discussed but does not explicitly teach the thickness of the biostructure. Wagner et al. teach an array of screening of biomolecular activity where biomolecules specific binding partner, e.g. antibodies, are immobilized on the microarray device. (See Figures 1-3) Wagner et al. teach the thickness of the solid support for

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immobilizing biomolecules are in range of 50 to 500 nm. (Col. 11, line 50-60) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Nova et al. with method of manufacturing microarray solid support as taught by Wagner et al. to have a thinner solid support for coating biomolecules since it is economical and convenient for the purposes of mass screening.

Response to Applicant's Arguments

8. Applicant argues that the none of the cited documents teach or suggest a biostructure that includes a nonporous latex-derived material that is formed by coalescence of latex derived by polymer particles. (See Remarks, page 9, last paragraph) Applicant's argument has been considered but is not persuasive.

First, as discussed in the beginning of this Office Action, it is not clear what kind of "coalescence" step applicant refers to for the formation of the latex particles. Applicant does not provide an example to show how to "coalescence" the latex particles. Rather, applicant merely describes such a phenomena in general. (See Specification, page 10, line 25-32)

Second, applicant asserts that "the *degree* of polymer particle coalescence can be altered by the presence of carbohydrates, or surface active agents, or by polymer particle composition, film formation temperature, and/or drying conditions" (See Specification, page 10, line 25-32)(emphasis added) The "coalescence" of particles is an inherent characteristic anticipated by either Thiagarajan et al., Cantell or Nova et al. reference since it is a natural attraction between any particles while in the preparation process to "coalescence", and the degree of particle coalescence may be varied by the presence of carbohydrates, surface active agents, or even by particle composition as asserted by the applicant.

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Furthermore, method of making a device does not carry patentable weight in a device claim. As long as the reference contains the same material as recited in the claim, the reference anticipates the claim. It is irrelevant how the material is made since such is not given patentable weight in the device/or apparatus claim.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

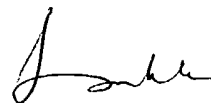
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641



April 15, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/16/04